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(54) Title of the invention	CARDIAC PACEMAKER FOR TREATING SUPERIOR VENTRICULAR TACHYCARDIA	
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SPECIFICATION

1. TITLE OF THE INVENTION

Cardiac Pacemaker for Treating Superior Ventricular Tachycardia

2. SCOPE OF PATENT CLAIMS

1. A cardiac pacemaker for treating superior ventricular tachycardia provided with electric current outputting means for applying a DC current intermittently to the atrial muscle when supraventricular tachycardia exceeds a specific upper limit rate.

3. Detail Expiration of the Invention

(Field of Technology)

Cardiac pacemakers send pulses to the myocardium to stimulate the myocardium to sustain a cardiac pulse. The cardiac pacemaker comprises a power supply, circuitry, and stimulant electrodes, and is a device that is typically used with a bradycardia patient (a patient with a disease wherein the cardiac pulse is abnormal with a cardiac pulse rate of less than 50 beats per minute); a cardiac pacemaker is implanted in the body of the patient to treat bradycardia through creating a cardiac pulse.

Cardiac pacemakers have been used clinically in since about 1960 the United States and Europe, and since about 1965 in Japan. While cardiac pacemakers are firmly established as a method of treating bradycardia, treatments have attempted for tachycardia as well (a disease wherein they cardiac pulse is abnormal with a cardiac pulse rate of more than 100 beats per minutes) through electrically stimulating the myocardium. However, at present, pacemakers for the treatment of tachycardia have not yet been established.

There are two types of tachycardia, supraventricular tachycardia (where the cause of the tachycardia is atrial) and ventricular tachycardia (where the cause of the tachycardia is ventricular). More than 90% of tachycardias are supraventricular tachycardias.

The present invention relates to cardiac pacemakers that are useful for the treatment of patients with supraventricular tachycardia.

(Prior Art)

Cardiac pacemakers for bradycardia are well established, and there are continual improvements targeting smaller devices with longer service lifetimes. The pacemakers of today send pulses automatically at a rate of 70 pulses per minute to the atrium cordis or the ventricular muscle when the cardiac pulse rate has fallen below a set rate (normally 70 peaks per minute). The normal electrical pulse is 5V for 0.5 ms.

The supraventricular tachycardia patients, who are the patients that are the subject of the present invention, are normally treated through the administration of medication or injections. If the medication is ineffectual, then an electrical treatment is performed using a cardiac pacemaker.

While implanted pacemakers automatically detect (sense) the tachycardia of the patient and automatically apply the stimulation of one or multiple pulses to the atrium cordis, at present the pacemakers

are pacemakers for supraventricular bradycardia. Many innovations have been made regarding the timing with which one or multiple stimuli are delivered. That is, research and development is underway regarding the timing, in the cardiogram of the patient, with which the pulse stimuli should be applied in order to correct tachycardia, where a large variety of cardiac pacemakers for treating supraventricular tachycardia are already available on the market. However, all of these devices are lacking in credibility in the treatment of supraventricular tachycardia, and a new device is desired.

(Objective)

The objective is to take advantage of the basic structure of the cardiac demand pacemaker that has been used conventionally, to provide a new type of cardiac pacemaker for treating tachycardia through applying a simple added means thereto.

(Structure)

The present invention relates to a cardiac pacemaker for treating supraventricular tachycardia, provided with electric current outputting means for applying a DC current intermittently to the atrial muscle, when supraventricular tachycardia exceeds a specific upper limit rate.

The present invention has a distinctive feature in that a DC current is applied automatically to the atrium cordis when there is tachycardia, and thus can be applied to ventricular demand pacemakers (VVI), P synchronous pacemakers (VDD), atrial demand pacemakers (AAI), A-V sequential pacemakers (DVI), and A-V universal pacemakers (DDD).

The aforementioned electric current outputting means simply applies a DC current intermittently; however, these means are preferably used so as to apply the current during the refractory period between approximately 100 and 300 ms after the R wave appears in the cardiogram schema in Fig. 4. (Hereinafter these means shall be referred to as the "R wave-synchronized DC current conduction.")

A normal pacemaker, for example, a VVI pacemaker is sealed in a casing. Approximately two thirds of the volume of the pacemaker is occupied by the battery, and the circuitry of the pacemaker is as shown in the diagram in Fig. 2.

The pacemaker amplifies the voltage of the cardiac contractions through the leads introduced into the ventricle to detect automatically the pulse frequency. The pacemaker contains a crystal oscillator, and if no pulse is generated within a specific amount of time after a detected pulse, the pacemaker generates a pulse automatically to cause the heart to contract. The pacemaker is programmed so that it does not generate a pulse if the heart of the patient contracts within a specific amount of time after the detected pulse. Because the voltages used in recent pacemakers are all about the same, the intensity of the stimulus pulse is determined by the pulse width. That is, the strength of the pulse is determined by the time duration of the pulse. The pulse is amplified and sent to the ventricular muscle through the leads (the ventricular electrodes). The present invention adds, to the conventional circuitry, an upper limit rate detecting part so as to apply a DC current to the atrium cordis when there is tachycardia.

The various functions of conventional ventricular pacemakers can be programmed (through remote control) even after the pacemaker has been implanted in the body, and the programmable features are as follows (Note that the numbers in parentheses indicate the values that can be changed through programming.):

(1) Pulse width (0.1, 0.2, 0.3, ... , 1.0 ms)
(2) Sensitivity (2.5, 5.0 mV)
(3) Voltage (2.5, 5.0 V)
(4) Rate (lower limit rate) 40, 50, 60, ... , 90 ppm)

The present invention adds, to the conventional ventricular pacemaker, means for detecting the ventricular pulse, and, in connection thereto, electric current outputting means having a DC current supply function for applying a DC current intermittently to the atrial muscle, and having an atrial lead for applying the DC current to the atrial muscle. For example, the parts marked with the asterisks in Fig. 2 (the upper limit rate detecting part, the DC current control circuit, the output circuit and the atrial electrodes) are the functions that have been added by the present invention to the typical ventricular pacemaker (a VVI pacemaker). Typically, pacemakers are entirely sealed in metal containers made from stainless steel or titanium in order to protect the electronic circuitry from moisture, such as bodily fluids; the metal casing also shields the circuitry from external electric fields so that they cannot penetrate into the chamber that is encased in an electrical conductor, and this is true for the present invention as well.

The present invention has a feature of a DC current being applied to the atrial wall through the atrial leads; the features that can be programmed regarding these atrial leads are listed below (Note that the values within the parentheses are the values that can be changed through programming.):

(1) Operation of the DC current for the atrial leads (ON/OFF)

If the operation of the DC current is turned OFF, then the device behaves exactly as a conventional ventricular pacemaker.

(2) There is a rate at which the tachycardia triggers the production of the DC current. This rate is known as the "upper limit." Three different rates can be set for the upper limit (for example, 145, 150, or 175

BPM [beats per minute]). A pulse (R wave) exceeding the set value is detected by the pacemaker through the ventricular leads, and acts as a trigger to supply the DC current intermittently to the atrial muscle.

(3) Selection of the DC voltage (5.0, 7.5, 10.0 V)

(4) Selection of either a DC current or an R wave-synchronized DC current (DC current or R wave synchronization).

(5) If R wave synchronization is selected, then there is a selection of the timing at which the DC current is applied after the R wave (100, 200, or 300 ms).

The present invention will be described in greater detail in reference to the figures. Note that while the description below includes various specific examples, the present invention is not limited thereby.

The method of implanting the pacemaker (1) into the body according to the present invention is essentially the same as in the conventional method, and is shown in Fig. 1.

When the pulse of the patient exceeds the upper limit rate that has been set, a DC current is automatically applied, for a duration of 10 seconds, to the atrial wall through an atrial lead (3) (See Fig. 1 through Fig. 3). Note: it is preferable that the DC current is not applied if the upper limit rate is exceeded only momentarily, but rather only when there is a pulse rate exceeds the upper limit rate for 10 seconds continuously, at which time a "Yes" signal should be outputted (See Fig. 3). The applied voltage can be programmed to be either 5.0 V, 7.5 V, or 10.0 V. After application of the DC voltage has been completed, the pacemaker waits for 10 seconds, and if the pulse rate of the patient is still in excess of the upper limit rate that has been programmed, then 10 V is applied for another 10 seconds. The impedance, when using platinum-indium electrodes with surface areas between 3 and 6 mm^2, is between 1000 and 2000 ohms, so there will be an electric current between 5 and 10 milliamps when 10 V are applied. This program is ineffective if the tachycardia of the patient is not resolved by the initial 10 seconds of electric current and the following 10 seconds of electric current at 10 V. In such case, it would be necessary to perform reprogramming. When used manually, the DC current can be applied any number of times. Fig. 3 is a program diagram envisioning an upper limit rate of 175 BPM and an additional voltage of 5.0 V. Fig. 4 shows standard type II inductive cardiogram schemas for the following situations: (i) when there is a normal sinus rhythm, (ii) when tachycardia occurs, (iii) when there is atrial fibrillation caused by the DC current, and (iv) when the DC current is terminated and there is again a normal sinus rhythm. The pacemaker detects the state in (ii) and automatically produces the atrial fibrillation shown in (iii) by applying the DC current, and when the 10-second application of the DC current has been completed, the state returns to (iv). While clinically this application of current is limited to only two times, the device can be modified so that the number of times that the DC current is applied automatically can be increased to three times, four times, or more.

The application of the DC current in the present device is, in principle, 10 seconds of continuous current initiated by the detection of tachycardia; however, in order to further increase the safety of the method in the present device, preferably a method is used wherein the DC current is applied in approximately 100 to 300 ms intervals after the R wave in the patients cardiogram, intermittently over an interval of approximately 10 seconds. The timing of approximately 100 to 300 ms after the occurrence of the R wave is the refractory period of the ventricular muscle, so that there would be no danger even if the DC current were applied in error to the ventricular muscle; however, if the DC current were applied at other times to the ventricular muscle, the results would be ventricular fibrillation, causing a loss of function of the ventricle, resulting in death.

The surface area of the atrial electrode is no more than 6 mm^2. When the current or the voltage is constant, smaller electrodes surface areas can produce atrial fibrillation more easily. However, if the electrode surface area is too small then the contact resistance with the tissue will be higher, and thus an atrial electrode surface area between 3 and 6 mm^2 is preferred.

In terms of the electrode material, platinum, platinum-indium, etc., is preferred due to the resistance to electrolysis. Platinum-indium is typically used for pacemaker electrodes and the like. Platinum-indium is also recommended as the material for the atrial electrodes in the present device.

When a DC current is applied to the atrial wall, atrial fibrillation can be produced easily at one or both electrodes. At this time, there is no difference in the atrial fibrillation threshold, regardless of whether the current is applied with the positive electrode or the negative electrode in contact with the atrial wall. Atrial fibrillation can be produced easily even when both the positive and negative electrodes are in contact with the atrium cordis, and a 5 mm separation between the electrodes is adequate.

While the objective is to treat supraventricular tachycardia through causing atrial fibrillation through the application of a DC current to the atrial wall, if a DC current is applied mistakenly to the ventricular wall, ventricular fibrillation will result, which is extremely dangerous for the patient, and may result

in death. Consequently, innovations that prevent the application of an electric current to the ventricle are essential. The following points should be considered in order to prevent such errors.

(1) Use the atrial electrodes only to apply DC current, and not for pacing or sensing. This simplifies the wiring of the atrial leads, making it possible to prevent the accidental application of a DC current to a ventricular lead.

(2) Use a design that enables the provisional application of DC current to the atrial electrodes using the programmer (the remote control unit). While this will induce atrial fibrillation, it will make it possible to confirm that there is no ventricular fibrillation.

(3) Shorten the atrial leads so that they cannot reach the ventricles easily.

(4) When connecting the atrial leads and the ventricular leads to the pacemaker, have different connector adapter shapes and wrapping. In other words, the atrial leads should not be able to connect to the ventricular side of the pacemaker unit, or the ventricular leads to the atrial side. This arrangement helps prevent the doctor from connecting the leads to the main unit incorrectly, thereby preventing the application of a DC current to the ventricle.

(5) When securing the atrial lead to the inner surface of the atrium cordis, the tip of the atrial lead may be connected to the right side of the right atrial wall at the opening of the superior vena cava. This is to increase the separation of the atrial electrode from the ventricle.

(6) When the atrial lead is inserted deeply into the auricle of the right atrium, and a DC current is applied to the wall of the auricle, the electric current will flow to the right ventricular wall of the right ventricular outflow tract, which has the potential of inducing ventricular fibrillation. Therefore, do not insert the atrial lead too deeply in the auricle of the right atrium.

(7) A screw-in lead is preferred as the lead for the atrium cordis. The lead tip is secured on the atrial wall endocardium. The electrode at the lead tip is a corkscrew shape. When the lead is inserted into the blood vessel and is pushed to reach the heart, the corkscrew-shaped portion of the electrode is retracted within the lead. When the lead tip is inserted into the appropriate part of the right atrium cordis, rotating the base of this lead 10 to 20 times will cause the corkscrew portion (the electrode) of the lead tip to extend, as shown in Fig. 5 (ii), and pierce the surface of the endocardium.

This lead has been on the market for 10 years, is completely reliable, and can also be used as the atrial lead in the present device.

(8) While the objective for the clinical use of the present device is supraventricular tachycardia, in addition to supraventricular tachycardia, there are also sick sinus syndrome, atrial flutter, latent WPW syndrome, and the like as disorders that can cause this. On the other hand, cases wherein the conduction of the accessory pathway in WPW syndrome is from the atrium cordis towards the ventricle, and cases of diseases of the atrioventricular nodal conduction wherein the refractory period is short can be thought of as cases wherein the use of the present device is contraindicated.

(Effects)

The present invention has provided a new type of pacemaker for treating tachycardia.

The pacemaker as set forth in the present invention has a simple structure, and, in particular, is absolutely more useful than the conventional type in terms of safety, particularly when used in a system wherein there is an electric current during the interval between 100 and 300 ms after the R wave.

4. Simple Description of Drawings

Fig. 1 is a model of a case wherein the pacemaker as set forth in the present invention has been implanted in a human body; Fig. 2 is a system diagram illustrating a specific example of a device as set forth in the present invention; Fig. 3 is a specific program for the use of the device as set forth in the present invention; Fig. 4 shows standard type II induction cardiogram schemas; and Fig. 5 is a cross-sectional diagram of one example of a screw-type lead that can be used in the present invention.

1: Pacemaker
2 Right Ventricular Lead
3: Right Atrial Lead
4: Right Atrium
5: Right Ventricle
6: Left Atrium
7: Left Ventricle

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Fig. 1

Fig. 2
[1] Ventricle Electrode
[2] Atrial Electrode
[3] Output Amplifier
[4] Diode to Prevent Excessive Power
[5] Crystal Oscillator
[6] Cardiac Voltage Amplifier
[7] Pulse Width Generator
[8] Clock Generator
[9] Output Pulse Generator
[10] Rate Generator
[11] Upper Limit Rate Detector
[12] Output Circuit
[13] DC Current Control Circuit (R Wave Synchronization Circuit)
[14] Refractory Period Generator

Fig. 3
[15] Greater than 175 BPM?
[16] Waited 10 Seconds?
[17] Apply 5 V for 10 Seconds.
[18] Greater than 175 BPM?
[19] Waited 10 Seconds?
[20] Apply 10 V for 10 Seconds.
[21] Greater than 175 BPM?

Fig. 4
P Wave
R Wave
I Wave